

AMENDED IN SENATE APRIL 11, 2011

**SENATE BILL**

**No. 431**

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**Introduced by Senator Emmerson**

February 16, 2011

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An act to amend Sections ~~4081~~, 4104, 4105, ~~and 4112~~ of 4112, and 4126.5 of, and to add Section 4126.7 to, the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 431, as amended, Emmerson. Pharmacies: regulation.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for administering and enforcing the provisions of that law, including the licensure of pharmacies, as defined, and nonresident pharmacies that ship, mail, or deliver controlled substances or dangerous drugs or devices, as defined, into this state. *The Under existing law, a reverse distributor is any person who acts as an agent for a pharmacy, drug wholesaler, manufacturer, or other entity by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. A knowing violation of the Pharmacy Law is a crime. Existing law provides for the registration of hazardous waste haulers, as defined.*

*This bill would prohibit a reverse distributor from accepting the return of dangerous drugs that have been dispensed to a patient that are later returned by the patient or patient's agent to a pharmacy, as specified, and would authorize only hazardous waste haulers to handle or dispose of those drugs.*

*Existing law requires that each pharmacy establish procedures for addressing the theft, diversion, or self-use of dangerous drugs by a licensed individual employed by or with the pharmacy, and that every*

*pharmacy report to the board within 30 days of the receipt or development of certain information affecting the ability of those individuals to practice the profession or occupation authorized by their license, as specified. Existing law requires an entity licensed by the board to retain records of the acquisition and disposition of dangerous drugs and devices in a specified manner. The law makes a knowing violation of its provisions a misdemeanor.*

*This bill would instead require a pharmacy to report and provide to the board, within 14 days of the receipt or development thereof, the information described above regarding the ability of licensed individuals employed by or with the pharmacy to practice the profession or occupation authorized by their license. The bill would require a pharmacy to conduct an audit of the theft, diversion, or self-use of dangerous drugs by a licensed individual employed by or with the pharmacy and provide, as specified, the board with a certified copy of the audit and its results. The bill would also require an entity licensed by the board to provide records to designated persons within 72 hours of the time of the request, unless that timeframe is extended by the board. The bill would prohibit a pharmacist whose license was revoked by the board to perform pharmacy duties, as specified, for a nonresident pharmacy.*

*Existing law requires all records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices to be at all times during business hours open to inspection by authorized officers of the law and preserved at least 3 years from the date of making. Existing law requires every person or entity who maintains a stock of dangerous drugs or dangerous devices to keep a current inventory.*

*This bill would require that any record pertaining to the return of dangerous drugs to a wholesaler, reverse distributor, or hazardous waste hauler include specified information, including the quantity or weight of the drugs returned.*

Because this bill would specify additional requirements under the Pharmacy Law, a violation of which is a crime, it would impose a state-mandated local program by creating additional crimes.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1     **SECTION 1.** *Section 4081 of the Business and Professions*  
2     *Code is amended to read:*

3     4081. (a) All records of manufacture and of sale, acquisition,  
4     or disposition of dangerous drugs or dangerous devices shall be  
5     at all times during business hours open to inspection by authorized  
6     officers of the law, and shall be preserved for at least three years  
7     from the date of making. A current inventory shall be kept by every  
8     manufacturer, wholesaler, pharmacy, veterinary food-animal drug  
9     retailer, physician, dentist, podiatrist, veterinarian, laboratory,  
10    clinic, hospital, institution, or establishment holding a currently  
11    valid and unrevoked certificate, license, permit, registration, or  
12    exemption under Division 2 (commencing with Section 1200) of  
13    the Health and Safety Code or under Part 4 (commencing with  
14    Section 16000) of Division 9 of the Welfare and Institutions Code  
15    who maintains a stock of dangerous drugs or dangerous devices.

16    (b) The owner, officer, and partner of a pharmacy, wholesaler,  
17    or veterinary food-animal drug retailer shall be jointly responsible,  
18    with the pharmacist-in-charge or designated  
19    representative-in-charge, for maintaining the records and inventory  
20    described in this section.

21    (c) The pharmacist-in-charge or designated  
22    representative-in-charge shall not be criminally responsible for  
23    acts of the owner, officer, partner, or employee that violate this  
24    section and of which the pharmacist-in-charge or designated  
25    representative-in-charge had no knowledge, or in which he or she  
26    did not knowingly participate.

27    (d) *Any record pertaining to the return of dangerous drugs to*  
28    *a wholesaler or provided to a reverse distributor shall document*  
29    *the quantity or weight of the drugs returned, the date the drugs*  
30    *were returned, and the name of the reverse distributor or*  
31    *wholesaler to whom the drugs were provided.*

32    (e) *Any record pertaining to the return of dangerous drugs to*  
33    *a hazardous waste hauler, as described in Section 117660 of the*  
34    *Health and Safety Code, shall list the volume in weight or*  
35    *measurement of the pharmaceutical waste returned, the date the*

1 *waste was returned, and the name of the hazardous waste hauler*  
2 *to whom the waste was provided.*

3 **SECTION 1.**

4 *SEC. 2.* Section 4104 of the Business and Professions Code is  
5 amended to read:

6 4104. (a) Every pharmacy shall have in place procedures for  
7 taking action to protect the public when a licensed individual  
8 employed by or with the pharmacy is discovered or known to be  
9 chemically, mentally, or physically impaired to the extent it affects  
10 his or her ability to practice the profession or occupation authorized  
11 by his or her license, or is discovered or known to have engaged  
12 in the theft, diversion, or self-use of dangerous drugs.

13 (b) Every pharmacy shall have written policies and procedures  
14 for addressing chemical, mental, or physical impairment, as well  
15 as theft, diversion, or self-use of dangerous drugs, among licensed  
16 individuals employed by or with the pharmacy.

17 (c) Every pharmacy shall report and provide to the board, within  
18 ~~30~~ 14 days of the receipt or development ~~of thereof~~, the following  
19 information with regard to any licensed individual employed by  
20 or with the pharmacy:

21 (1) Any admission by a licensed individual of chemical, mental,  
22 or physical impairment affecting his or her ability to practice.

23 (2) Any admission by a licensed individual of theft, diversion,  
24 or self-use of dangerous drugs.

25 (3) Any video or documentary evidence demonstrating chemical,  
26 mental, or physical impairment of a licensed individual to the  
27 extent it affects his or her ability to practice.

28 (4) Any video or documentary evidence demonstrating theft,  
29 diversion, or self-use of dangerous drugs by a licensed individual.

30 (5) Any termination based on chemical, mental, or physical  
31 impairment of a licensed individual to the extent it affects his or  
32 her ability to practice.

33 (6) Any termination of a licensed individual based on theft,  
34 diversion, or self-use of dangerous drugs.

35 (d) The pharmacy shall conduct an audit to determine the  
36 quantity and type of dangerous drugs stolen, diverted, or used by  
37 a licensed individual employed by or with the pharmacy. The  
38 pharmacy shall submit to the board a ~~certified~~ copy of the audit  
39 within 30 days of the receipt or development of information *initial*

1 *report to the board regarding the evidence described in paragraph*  
2 ~~(4)~~ of subdivision (c).

3 (e) Anyone making a report authorized or required by this  
4 section shall have immunity from any liability, civil or criminal,  
5 that might otherwise arise from the making of the report. Any  
6 participant shall have the same immunity with respect to  
7 participation in any administrative or judicial proceeding resulting  
8 from the report.

9 ~~SEC. 2.~~

10 SEC. 3. Section 4105 of the Business and Professions Code is  
11 amended to read:

12 4105. (a) All records or other documentation of the acquisition  
13 and disposition of dangerous drugs and dangerous devices by any  
14 entity licensed by the board shall be retained on the licensed  
15 premises in a readily retrievable form.

16 (b) The licensee may remove the original records or  
17 documentation from the licensed premises on a temporary basis  
18 for license-related purposes. However, a duplicate set of those  
19 records or other documentation shall be retained on the licensed  
20 premises.

21 (c) The records required by this section shall be retained on the  
22 licensed premises for a period of three years from the date of  
23 making.

24 (d) Any records that are maintained electronically shall be  
25 maintained so that the pharmacist-in-charge, the pharmacist on  
26 duty if the pharmacist-in-charge is not on duty, or, in the case of  
27 a veterinary food-animal drug retailer or wholesaler, the designated  
28 representative on duty, shall, at all times during which the licensed  
29 premises are open for business, be able to produce a hard copy  
30 and electronic copy of all records of acquisition or disposition or  
31 other drug or dispensing-related records maintained electronically.

32 (e) (1) Notwithstanding subdivisions (a), (b), and (c), the board,  
33 may upon written request, grant to a licensee a waiver of the  
34 requirements that the records described in subdivisions (a), (b),  
35 and (c) be kept on the licensed premises.

36 (2) A waiver granted pursuant to this subdivision shall not affect  
37 the board's authority under this section or any other provision of  
38 this chapter.

39 (f) When requested by an authorized officer of the law or by an  
40 authorized representative of the board, the owner, corporate officer,

1 or manager of an entity licensed by the board shall provide the  
2 board with the requested records within 72 hours of the time the  
3 request was made. The entity may request in writing an extension  
4 of this timeframe for a period not to exceed 14 days from the date  
5 the records were requested. A request for an extension of time is  
6 subject to the approval of the board.

7 ~~SEC. 3.~~

8 *SEC. 4.* Section 4112 of the Business and Professions Code is  
9 amended to read:

10 4112. (a) Any pharmacy located outside this state that ships,  
11 mails, or delivers, in any manner, controlled substances, dangerous  
12 drugs, or dangerous devices into this state shall be considered a  
13 nonresident pharmacy.

14 (b) A person may not act as a nonresident pharmacy unless he  
15 or she has obtained a license from the board. The board may  
16 register a nonresident pharmacy that is organized as a limited  
17 liability company in the state in which it is licensed.

18 (c) A nonresident pharmacy shall disclose to the board the  
19 location, names, and titles of (1) its agent for service of process in  
20 this state, (2) all principal corporate officers, if any, (3) all general  
21 partners, if any, and (4) all pharmacists who are dispensing  
22 controlled substances, dangerous drugs, or dangerous devices to  
23 residents of this state. A report containing this information shall  
24 be made on an annual basis and within 30 days after any change  
25 of office, corporate officer, partner, or pharmacist.

26 (d) All nonresident pharmacies shall comply with all lawful  
27 directions and requests for information from the regulatory or  
28 licensing agency of the state in which it is licensed as well as with  
29 all requests for information made by the board pursuant to this  
30 section. The nonresident pharmacy shall maintain, at all times, a  
31 valid unexpired license, permit, or registration to conduct the  
32 pharmacy in compliance with the laws of the state in which it is a  
33 resident. As a prerequisite to registering with the board, the  
34 nonresident pharmacy shall submit a copy of the most recent  
35 inspection report resulting from an inspection conducted by the  
36 regulatory or licensing agency of the state in which it is located.

37 (e) All nonresident pharmacies shall maintain records of  
38 controlled substances, dangerous drugs, or dangerous devices  
39 dispensed to patients in this state so that the records are readily  
40 retrievable from the records of other drugs dispensed.

1 (f) Any pharmacy subject to this section shall, during its regular  
2 hours of operation, but not less than six days per week, and for a  
3 minimum of 40 hours per week, provide a toll-free telephone  
4 service to facilitate communication between patients in this state  
5 and a pharmacist at the pharmacy who has access to the patient's  
6 records. This toll-free telephone number shall be disclosed on a  
7 label affixed to each container of drugs dispensed to patients in  
8 this state.

9 (g) A nonresident pharmacy shall not permit a pharmacist whose  
10 license has been revoked by the board to manufacture, compound,  
11 furnish, sell, dispense, or initiate the prescription of a dangerous  
12 drug or dangerous device, or to provide any pharmacy-related  
13 service, to a person residing in California.

14 (h) The board shall adopt regulations that apply the same  
15 requirements or standards for oral consultation to a nonresident  
16 pharmacy that operates pursuant to this section and ships, mails,  
17 or delivers any controlled substances, dangerous drugs, or  
18 dangerous devices to residents of this state, as are applied to an  
19 in-state pharmacy that operates pursuant to Section 4037 when the  
20 pharmacy ships, mails, or delivers any controlled substances,  
21 dangerous drugs, or dangerous devices to residents of this state.  
22 The board shall not adopt any regulations that require face-to-face  
23 consultation for a prescription that is shipped, mailed, or delivered  
24 to the patient. The regulations adopted pursuant to this subdivision  
25 shall not result in any unnecessary delay in patients receiving their  
26 medication.

27 (i) The registration fee shall be the fee specified in subdivision  
28 (a) of Section 4400.

29 (j) The registration requirements of this section shall apply only  
30 to a nonresident pharmacy that ships, mails, or delivers controlled  
31 substances, dangerous drugs, and dangerous devices into this state  
32 pursuant to a prescription.

33 (k) Nothing in this section shall be construed to authorize the  
34 dispensing of contact lenses by nonresident pharmacists except as  
35 provided by Section 4124.

36 *SEC. 5. Section 4126.5 of the Business and Professions Code*  
37 *is amended to read:*

38 4126.5. (a) A pharmacy may furnish dangerous drugs only to  
39 the following:

1 (1) A wholesaler owned or under common control by the  
2 wholesaler from whom the dangerous drug was acquired.

3 (2) The pharmaceutical manufacturer from whom the dangerous  
4 drug was acquired.

5 (3) A licensed wholesaler acting as a reverse distributor.

6 (4) Another pharmacy or wholesaler to alleviate a temporary  
7 shortage of a dangerous drug that could result in the denial of  
8 health care. A pharmacy furnishing dangerous drugs pursuant to  
9 this paragraph may only furnish a quantity sufficient to alleviate  
10 the temporary shortage.

11 (5) A patient or to another pharmacy pursuant to a prescription  
12 or as otherwise authorized by law.

13 (6) A health care provider that is not a pharmacy but that is  
14 authorized to purchase dangerous drugs.

15 (7) To another pharmacy under common control.

16 (8) *A hazardous waste hauler, as described in Section 117660*  
17 *of the Health and Safety Code, for the sole purpose of waste*  
18 *disposal of pharmaceutical waste returned to the pharmacy by a*  
19 *patient or patient's agent.*

20 (b) Notwithstanding any other provision of law, a violation of  
21 this section may subject the person or persons who committed the  
22 violation to a fine not to exceed the amount specified in Section  
23 125.9 for each occurrence pursuant to a citation issued by the  
24 board.

25 (c) Amounts due from any person under this section on or after  
26 January 1, 2005, shall be offset as provided under Section 12419.5  
27 of the Government Code. Amounts received by the board under  
28 this section shall be deposited into the Pharmacy Board Contingent  
29 Fund.

30 (d) For purposes of this section, "common control" means the  
31 power to direct or cause the direction of the management and  
32 policies of another person whether by ownership, by voting rights,  
33 by contract, or by other means.

34 *SEC. 6. Section 4126.7 is added to the Business and Professions*  
35 *Code, to read:*

36 *4126.7. (a) A reverse distributor shall not accept the return*  
37 *of dangerous drugs that have been dispensed to a patient that are*  
38 *later returned by the patient or the patient's agent to the pharmacy*  
39 *or another licensed entity.*



1     ***(b) Dangerous drugs returned by a patient or a patient’s agent***  
2     ***to a pharmacy, if accepted by the pharmacy, may be picked up or***  
3     ***handled only by a hazardous waste hauler, as described in Section***  
4     ***117660 of the Health and Safety Code.***

5     ***(c) For purposes of this section, “dispensed” means that the***  
6     ***dangerous drugs have been provided to the patient or patient’s***  
7     ***agent and taken from a pharmacy.***

8     ~~SEC. 4.~~

9     ***SEC. 7.*** No reimbursement is required by this act pursuant to  
10    Section 6 of Article XIII B of the California Constitution because  
11    the only costs that may be incurred by a local agency or school  
12    district will be incurred because this act creates a new crime or  
13    infraction, eliminates a crime or infraction, or changes the penalty  
14    for a crime or infraction, within the meaning of Section 17556 of  
15    the Government Code, or changes the definition of a crime within  
16    the meaning of Section 6 of Article XIII B of the California  
17    Constitution.